Challenges in Development and Use of Rapid Diagnostics in Healthcare Settings: A Clinical (Pathology) Perspective

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October 13, 2022

Infectious Disease Testing: Suplexing the Multiplex

Upper limit of rapid multiplex testing continues to grow to 30+ targets… with turnaround times of ~1 hour, and ~1 min hands-on time

BioFire® FilmArray®

Pneumonia Panel *plus* Investigational Use Only

33 Targets

Bacteria
- *Acinetobacter calcoaceticus-baumannii* complex
- *Serratia marcescens*
- *Proteus* spp.
- *Klebsiella pneumoniae* group
- *Enterobacter aerogenes*
- *Enterobacter cloacae* complex
- *Escherichia coli*
- *Haemophilus influenzae*
- *Moraxella catarrhalis*
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Streptococcus pneumoniae*
- *Klebsiella oxytoca*
- *Streptococcus pyogenes*
- *Streptococcus agalactiae*

Atypical Bacteria
- *Legionella pneumophila*
- *Mycoplasma pneumoniae*
- *Chlamydia pneumoniae*

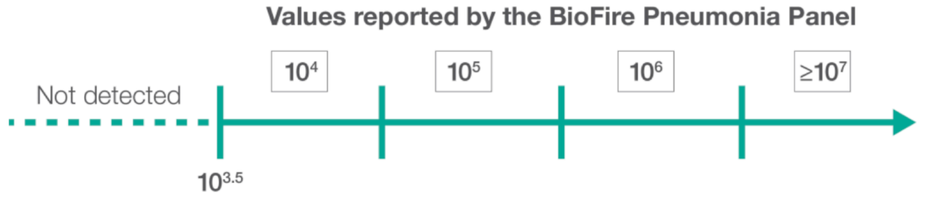
Viruses
- Influenza A
- Influenza B
- Respiratory Syncytial Virus
- Human Rhinovirus/Enterovirus
- Human Metapneumovirus
- Parainfluenza Virus
- Adenovirus
- Coronavirus
- ~~Middle East Respiratory Syndrome Coronavirus~~

Antimicrobial Resistance Genes
- *mecA/C* and MREJ
- KPC
- NDM
- OXA-48-like
- CTX-M
- VIM
- IMP

Sample Type: Sputum, Endotracheal aspirate, Bronchoalveolar Lavage, and mini-BAL

FDA authorized

Baked-in quantitation



The PN panel demonstrated a combined 96.2% positive percent agreement (PPA) and 98.1% negative percent agreement (NPA) for the qualitative identification of 15 bacterial targets compared to routine bacterial culture.

Murphy et al. JCM 2020

Molecular microbiology diagnostics' hottest trend is…

CPT	Analytes	2022 National Limitation Amount
87631	3-5	$143
87632	6-11	$218
87633	12-25	$417

Molecular microbiology diagnostics' hottest trend is…Family Feud.

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Uproxx

Thoughts

- Flexibility matters
  - These panels end up in so many different contexts, from quaternary hospital with AMR experts/committees to community hospital with relevant antibiotics not on formulary.
- Interpretation matters.
  - Most clinicians do not speak AMR gene, so you have to relate directly to antibiotic - another advantage of phenotypic testing.
- Validation has to be tied to number of markers, but charge may not directly need to. This has been the major issue in multiplex diagnostics to date. Please don’t make us play Family Feud with AMR testing.
- No way to pass along costs for highly complex inpatient testing with expensive reagents.
- Make Validation Easy Again
  - CDC/FDA to make bacterial panels to validate all these targets, distribute through BEI?…very hard to get all the required isolates/specimens to cover all these AMR genes
- Divorcing AMR detection from given species is a new’ish approach, so you have to do some large studies to show that it works and matters.
  - Is this 24-hour period the critical period for the development of antibiotic resistance?